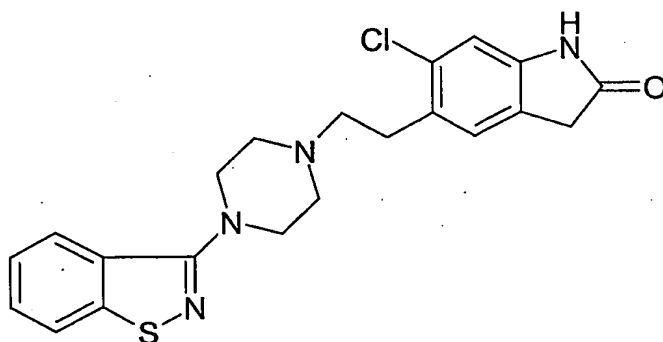


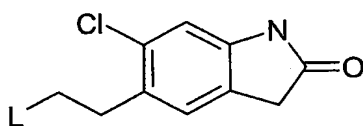
**WE CLAIM:**

1. A process for the preparation of ziprasidone base of Formula I, or a salt thereof,

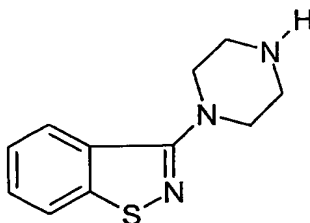
**FORMULA I**

the process comprising:

reacting a compound of Formula II,

**FORMULA II**

wherein L is a leaving group, with 1-(1,2-benzisothiazol-3-yl)piperazine of Formula III,

**FORMULA III**

in water in absence of a base to form a mixture;

heating the resultant mixture to from about 50°C to reflux temperature; and

isolating the ziprasidone base of Formula I, or a salt thereof.

- 1 2. The process of claim 1, wherein the leaving group L is selected from the group  
2 consisting of chloro, bromo, iodo, mesyloxy, tosyloxy or acetyloxy.
- 1 3. The process of claim 1, further comprising heating the mixture in the presence of  
2 an organic solvent.
- 1 4. The process of claim 3, wherein the organic solvent comprises one or more of  
2 alcohols, ketones, polar aprotic solvents, esters, or mixtures thereof.
- 1 5. A process for the preparation of substantially pure ziprasidone base, the process  
2 comprising:
  - 3 obtaining a suspension of ziprasidone in one or more solvents;
  - 4 heating the suspension to get a clear solution; and
  - 5 recovering the substantially pure ziprasidone by the removal of the solvent.
- 1 6. The process of claim 5, wherein the solvent comprises one or more of lower  
2 alkanol, ether, ketone, chlorinated hydrocarbon, polar aprotic solvent, water, or mixtures  
3 thereof.
- 1 7. The process of claim 6, wherein the lower alkanol comprises one or more of  
2 methanol, ethanol, n-propanol, and isopropanol.
- 1 8. The process of claim 6, wherein the ether comprises one or both of  
2 tetrahydrofuran, and 1,4-dioxane.
- 1 9. The process of claim 6, wherein the ketone comprises one or more of acetone,  
2 ethyl methyl ketone, methyl isobutyl ketone, and diisobutyl ketone.
- 1 10. The process of claim 6, wherein the chlorinated hydrocarbon comprises one or  
2 more of chloroform, dichloromethane, and 1,2-dichloroethane.
- 1 11. The process of claim 6, wherein the polar aprotic solvent comprises one or more of  
2 N,N-dimethylformamide, N,N-dimethylacetamide, dimethylsulfoxide, acetonitrile, and N-  
3 methylpyrrolidone.
- 1 12. The process of claim 5, wherein the suspension is heated from about 40°C to reflux  
2 temperature.

- 1 13. The process of claim 5, wherein removing the solvent comprises one or more of  
2 distillation, distillation under vacuum, evaporation, filtration, filtration under vacuum,  
3 decantation, and centrifugation.
- 1 14. The process of claim 13 further comprising adding additional solvent before  
2 removing the solvent.
- 1 15. The process of claim 5, wherein the substantially pure ziprasidone, or a salt thereof  
2 is recovered from the solution by distillation.
- 1 16. The process of claim 15, wherein the distillation is carried out under vacuum.
- 1 17. The process of claim 5, wherein the substantially pure ziprasidone is recovered  
2 from the solution by filtration.
- 1 18. The process of claim 5, further comprising additional drying of the product  
2 obtained.
- 1 19. The process of claim 5, further comprising cooling before removing the solvent.
- 1 20. Ziprasidone base having a purity of more than 99.8% wherein total impurities are  
2 less than 0.2% when determined by HPLC.
- 1 21. Ziprasidone base having a purity of more than 99.9% wherein total impurities are  
2 less than 0.1% when determined by HPLC.
- 1 22. A process for the preparation of substantially pure ziprasidone hydrochloride, the  
2 process comprising:
- 3 obtaining a suspension of ziprasidone in one or more solvents;  
4 contacting the suspension with hydrogen chloride to form a solid; and  
5 isolating the ziprasidone hydrochloride in substantially free form.
- 1 23. The process of claim 22, wherein the solvent comprises one or more of lower  
2 alkanols, chlorinated hydrocarbons, aromatic hydrocarbons, polar aprotic solvents, ethers,  
3 ketones, or mixtures thereof.
- 1 24. The process of claim 22, wherein the solid is washed with water, polar aprotic  
2 solvent, lower alkanol, ether, or mixtures thereof before isolation.

- 1 25. The process of claim 24, wherein the solid is washed till the washings are free of  
2 any acidity.
- 1 26. The process of claim 22, further comprising additional drying of the product  
2 obtained.
- 1 27. The process of claim 22, further comprising forming the product obtained into a  
2 finished dosage form.
- 1 28. Ziprasidone hydrochloride having a purity of more than 99.8% with total  
2 impurities less than 0.2% when determined by HPLC.
- 1 29. Ziprasidone hydrochloride having a purity of more than 99.9% with total  
2 impurities less than 0.1% when determined by HPLC.
- 1 30. A pharmaceutical composition comprising a therapeutically effective amount of  
2 substantially pure ziprasidone hydrochloride, and one or more pharmaceutically  
3 acceptable carriers, excipients or diluents.
- 1 31. A method of treating schizophrenia in a warm-blooded animal, the method  
2 comprising providing a dosage form to the warm-blooded animal that includes  
3 substantially pure ziprasidone hydrochloride.